

## **REMARKS**

Claims 39-53 and 67-74 are currently pending in the application. Applicants amend independent Claims 39, 47, and 67. Support for these amendments can be found in lines 11-13 on page 12 of the specification as filed. The Final Office Action of December 7, 2009 (Final Office Action) rejects pending Claims 39-53 and 67-74 on grounds relating to anticipation. The rejections of Claims 39-53 and 67-74 are traversed. Applicants respond to the rejections as subsequently recited herein and respectfully request reconsideration and further examination. The Applicant also respectfully requests an Examiner Interview to discuss the subject of this submission at the Examiner's earliest convenience.

## **ARGUMENTS**

### A. 35 U.S.C. § 102(e) rejection of pending claims 39-53 and 67-74 as being anticipated by *Whitcher et al.* (U.S. Pub. No. US 2003/0018381).

The Examiner has rejected Claims 39-53 and 67-74 as being anticipated by *Whitcher* under 35 U.S.C. §102(e). The Applicants traverse these rejections, for the reasons set forth below.

As amended, independent Claims 39, 47, and 67 require vacuum depositing a film “under at least one vacuum deposition process condition selected from at least one of chamber pressure, deposition pressure, and partial pressure of a process gas, said at least one process condition optimized to” minimize or substantially eliminate formation of chemical and/or “intra- and intergranular precipitates in the bulk material.” The Applicants assert that *Whitcher* does not disclose selecting a process condition of chamber pressure, deposition pressure, or partial pressure of a process gas, where the selected process condition is optimized to minimize or substantially eliminate formation of chemical and/or intra- and inter-granular precipitates in the bulk material. As such, the Applicants respectfully request that the Examiner withdraw the §102(e) rejections of independent Claims 39, 47, and 67 accordingly.

Firstly, *Whitcher* does not disclose, teach, or suggest selecting a process condition of chamber pressure, deposition pressure, or partial pressure of a process gas, where the selected process condition is optimized to minimize or substantially eliminate formation of chemical and intra- and inter-granular precipitates in the bulk material. The Examiner has failed to recite any

disclosure in Whitcher of such selection of a process condition to minimize formation of precipitates in the bulk material. The only discussion related to utilization of different reaction chamber pressures in Whitcher is in paragraph [0035], which relates entirely to the useful source to substrate distance changing with the chamber pressure (not that optimizing such chamber pressure may minimize formation of granular precipitates).

Further, Whitcher continues to lack any disclosure related to optimizing a selected process condition so as to minimize the formation of granular precipitates. Applicants continue to traverse the Examiner's improper assertion that the Applicants' specification admits that standard vapor deposition methodologies achieves the desired minimization of granular precipitates of the Applicants' invention. This position fundamentally ignores the clear thrust of the Applicants' disclosure, which teaches controlling specific process conditions of vapor deposition to achieve the desired minimization of granular precipitates.

The Examiner improperly recites a portion of the Applicants' specification as an admission that the mere selection of vapor deposition significantly reduces or virtually eliminates the inter- and intra-granular precipitates in the bulk material. The BPAI decision, at finding of fact 7, repeats the edited quotation from the Examiner's answer to the appeal. The quote, as presented by the BPAI, is "[v]apor deposition of the inventive endoluminal stent . . . significantly reduces or virtually eliminates inter- and intra-granular precipitates in the bulk material" and "the need to control precipitates for mechanical properties is eliminated." (Spec. pg. 14, lines 19-25)

In full, the quoted section reads:

Vapor deposition of the inventive endoluminal stent, in accordance with a preferred embodiment of the present invention, significantly reduces or virtually eliminates inter- and intra-granular precipitates in the bulk material. It is common practice in the nickel-titanium endoluminal device industry to control transition temperatures and resulting mechanical properties by altering local granular nickel-titanium ratios by precipitation regimens. In the present invention, the need to control precipitates for mechanical properties is eliminated.

(Spec. pg. 14, lines 19-25) (emphasis added) The portion of the quote omitted by the Examiner and the BPAI makes it entirely clear that Applicants do not merely indicate that it is the mere use of vapor deposition that results in the reduction or near elimination of inter- and intra-granular precipitates in the bulk material. Rather, it is the selection of an optimized set of process

conditions of a specific embodiment of the Applicants' invention by which inter- and intra-granular precipitates are significantly reduced or virtually eliminated. This is contrary to the BPAI's prior decision (see Decision, 1st appeal, at 10), and the present decision (see Decision, 2nd appeal, at 10), both of which rely upon the Examiner's incorrect and selective reading of the Applicants' specification.

As emphatically stated in numerous previous responses, the Applicants do not simply point to a vacuum deposition process as the means for minimizing precipitates and other material properties. First, if it was true that merely using vacuum deposition minimizes precipitates, then the annealing step in the prior art vacuum deposition processes would have been unnecessary, as that step was introduced in order to drive out the precipitates formed during deposition. The Applicants' specification states that its inventive process (i.e., the specifically controlled process conditions that minimize granular precipitates) does not form precipitates, and hence eliminates the need for a post-processing annealing step. Second, if it was true that the vapor deposition process alone controlled the material properties, as the Examiner suggests, then all of the material properties would be *collectively* minimized or controlled simply by using the vacuum deposition process. As discussed above, this is untrue. Finally, Applicants' vacuum deposition process conditions are selected to minimize (or substantially eliminate) *the formation of* granular precipitates. Applicants' inventive method does not merely reduce the size of precipitates (minimize precipitates) as suggested by the Examiner, rather the method prevents the formation of precipitates in the first instance and during deposition. Thus, Applicants' disclosure does not simply point to a vacuum deposition process as the means for minimizing precipitates and other material properties.

Contrary to the Examiner's contention, Whitcher does not teach "inherently controlling and minimizing material properties such as granular precipitates just as much as the Applicants are." First, Applicants assert that granular precipitates are not categorized as one of the many "materials properties" that are collectively controlled by deposition, as the Examiner contends. [Emphasis added]. With respect to the definition of "materials properties" Applicants' specification recites:

The term "material properties" is intended to encompass physical properties, including without limitation, elasticity, tensile strength, mechanical properties, hardness, bulk and/or surface grain size, grain composition, and grain boundary size, intra and inter-

granular precipitates.

Present Application, p. 10, Lines 12-16.

The specification does not disclose that all of the listed properties are collectively controlled by deposition. Rather, as the Applicants state in the specification, the “desired material properties” are controlled by vacuum deposition process conditions. See Specification at 11, Line 9. Applicants’ listing of the physical properties that encompass “material properties” is simply a list of properties that may be controlled. All properties of a material are not cooperatively controlled or controlled as a group by deposition. For example, the process conditions selected to increase hardness are not the same process conditions selected to increase elasticity or the same process conditions selected to set a transition temperature.

Further, the Examiner contends that because Whitcher discloses use of the same vacuum deposition process (sputtering, ion beam, etc.), use of the same materials, and that deposition processes control material properties, then Whitcher inherently controls granular precipitates. This reasoning is flawed. First, Applicants submit that it is not sufficient for the Examiner to base an anticipation rejection relying on inherency on broad generalizations regarding the prior art. The Examiner has failed to provide any disclosure in Whitcher that clearly and specifically provides the elements of the claims currently rejected, either expressly or inherently. Second, as discussed above, the “material properties” are not collectively controlled by the deposition process. Finally, by way of analogy, the Examiner argues that to make a cookie, if one discloses use of the same cooking methodology (i.e. an oven, stove, microwave), use of the same ingredients, and that the oven controls cookie properties, then the softness of the cookie is inherently controlled or the color of the cookie is inherently controlled... this is a severe flaw in logic and reasoning. There are process conditions that would directly influence the resulting properties of the cookie such as the cooking time, temperature, placement in the oven (height and lateral distance from heat source), or the baking surface. A change in any of these conditions could affect the softness or color of the cookie. Thus, using the same process methodology and materials cannot render a property inherent.

Nothing in Whitcher discloses, teaches, or suggests that selection of particular process conditions – selected from at least one of chamber pressure, deposition pressure, and partial pressure of a process gas during vapor deposition – serves to minimize formation of inter- and

intra-granular precipitates. The Examiner's entire argument relies upon the supposition that preselection of a process condition is equivalent to selecting a process condition that minimizes formation of inter- and intra-granular precipitates. The Applicants fail to understand the Examiner's argument that "selected to minimize" is analogous to preselected or predetermined, for which the Examiner cites *Ferguson Beauregard/Logic Controls v. Mega Systems*, 350 F.3d 1327, 1338, 69 USPQ2d 1001, (Fed. Cir. 2003), presumably from MPEP 2111.01. This case is one of a number recited in the MPEP supporting the proposition that "[i]t is the use of the words in the context of the written description and customarily by those skilled in the relevant art that accurately reflects both the "ordinary" and the "customary" meaning of the terms in the claims;" or more generally "plain meaning" refers to the ordinary and customary meaning given to the term by those of ordinary skill in the art. It would fly in the face of "plain meaning" to reinterpret "selected to minimize" as equivalent to "preselected." While a condition that is "selected to minimize" might be preselected, it does not follow that simply because a condition is preselected it thus is selected to minimize. The Examiner's interpretation of the claim limitation improperly ignores the explicit claim language "selected to minimize." "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970)." MPEP 2143.03. By selectively reading out the words "to minimize" from "selected to minimize," the Examiner has arbitrarily chosen to ignore an explicit limitation of the independent claims, without any recitation to indicate why the plain meaning of "selected to minimize" is instead limited to "preselected."

In addition, the only condition Whitcher indicates as having an impact on controlling impurities is the actual control of particular mass-weight species that are targeted at the substrate. No other process conditions are indicated by Whitcher as amenable to influencing the formation of granular precipitates. What is claimed is not "controlling" the granular precipitates but "minimizing" granular precipitates. Whitcher does not disclose vacuum depositing a film "under at least one vacuum deposition process condition selected from at least one of chamber pressure, deposition pressure, and partial pressure of a process gas, said at least one process condition selected to substantially eliminate formation of chemical and intra- and intergranular precipitates in the bulk material." As such, the Applicants assert that the amendments to independent Claims 39, 47, and 67 have overcome the 102(e) rejection of those claims over Whitcher.

As to dependent Claims 40-46, 48-53, and 68-74, these claims depend from non-anticipated independent Claims 39, 47, and 67. Because these dependent claims set forth additional limitations beyond the independent claims, they are also non-anticipated by Whitcher. As such, the Applicants respectfully request that the Examiner withdraw the rejections of dependent Claims 40-46, 48-53, and 68-74 accordingly.

*Whitcher's selection of a process condition does not inherently minimize precipitates*

According to the Examiner in the Final Office Action mailed on December 7, 2009:

Additionally, Whitcher discloses selection of a process condition. Whitcher discloses selection of a temperature, pressure, and rate during deposition, therefore, inherently the precipitates are being controlled, since amount and size of the granular precipitates are dependent upon temp, pressure, and rate (general process conditions of vacuum deposition, which applicant has disclosed to be the method of minimizing precipitates), and upon selection of these conditions, one has controlled the crystal structure outcome of the metal, hence controlled how much formation of precipitates has occurred. Because Whitcher has disclosed a temperature, pressure, and rate, hence the material properties are preselected and are being controlled by the selection. Also, every metal has a specific granular makeup, including precipitates, and just by the user selecting a specific material to be deposited, the user is controlling the grain size, grain phase, granular precipitates, composition, and binding sites etc.

Final Office Action, dated December 7, 2009 p. 9.

Applicants submit that it is not sufficient for the Examiner to base an anticipation rejection relying on inherency on broad generalizations regarding the prior art.

"To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " In re Robertson, 169 F.3d 743, 745 (Fed. Cir. 1999) "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." Ex parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990)

See MPEP §2112.

The Examiner has failed to provide any disclosure in Whitcher that clearly and specifically provides the elements of the claims on appeal, either expressly or inherently. Applicants respectfully assert that Whitcher merely states conditions selected, i.e., chamber

pressure, deposition rate, without any suggestion that those conditions may be controlled in such a manner as to minimize precipitate formation in a crystalline film or even that a crystalline film is formed as a result of the specific selected conditions. In fact, none of the Examples found in Whitcher contain any statement or suggestion that the vacuum deposited film is crystalline, or that precipitate formation is, in fact, controlled. Moreover, Applicants submit that the Examiner has not explained, by presenting a preponderance of evidence, or any evidence, why a person of ordinary skill in the art would recognize that the allegedly inherent characteristic necessarily flows from the teachings of Whitcher. To the extent that the Examiner's opinion is based on her personal knowledge, Applicant requests under 37 C.F.R. §1.104(d)(2) that Examiner provide such information specifically and with support by a reference, all presented by affidavit of the Examiner.

For at least these reasons, Applicants submit that pending Claims 39-53 and 67-74 are distinguished from and patentable over the prior art cited and of record.

*Process conditions selected to minimize formation of chemical and intra and inter-granular precipitates is not vague and arbitrary and the Examiner has not properly considered the limitation*

According to the Examiner in the Final Office Action mailed on December 7, 2009:

[A]pplicant has claimed "process conditions selected to minimize formation of chemical and intra and inter-granular precipitates", however they have not claimed to what extent (numerical value) such properties are minimized to. No numerical amount has been assigned to "minimized". It is vague and arbitrary what amount "minimize" is and how it should be examined. It is unclear how to interpret such a word, with no exact value. As best as can be interpreted, Whitcher is believed to have "minimized" formation of precipitates, since the disclosed film may be crystalline upon deposition, since crystalline, would have no precipitates.

Final Office Action dated December 7, 2009, p. 10. The Examiner complains that "minimize" is vague and arbitrary; however, the Examiner has not rejected Claim 39 on any basis under 35 U.S.C. §112, second paragraph for indefiniteness. More so, a claim limitation which is considered indefinite cannot be disregarded. MPEP § 2143.03. The reaction products formed from a solid solution under increased thermal conditions of vacuum deposition are precipitates; they are driven from the solid solution resulting in the formation of the reaction products outside the solid solution, i.e. the metal crystalline structure. Minimizing the formation of precipitates in

a metal alloy minimizes the solid solution reaction products from forming under increased thermal conditions during vacuum deposition. “Minimize” generally means “reduce or keep to a minimum”. (www.merriam-webster.com, last accessed May 6, 2010.) Thus, the claim term “minimize intra- and inter-granular precipitates” would generally mean reduce or keep the precipitates to a minimum. The Examiner’s confusion of “minimize” belies the Examiner’s point that Whitcher’s vacuum deposition process is selected to minimize formation of chemical and intra and inter-granular precipitates, as the Examiner has not properly construed the limitation “process conditions selected to minimize formation of chemical and intra and inter-granular precipitates”; thus how can the Examiner properly conclude that Whitcher selects any vacuum deposition process conditions to minimize the formation of precipitates. Therefore, the process conditions selected to minimize formation of chemical and intra and inter-granular precipitates is not vague and arbitrary, and the Examiner has not properly considered the “vacuum deposition process is selected to minimize formation of chemical and intra and inter-granular precipitates”, and Whitcher fails to anticipate the limitation according to the Examiner’s rationale.

For at least these reasons, Applicants submit that pending Claims 39-53 and 67-74 are distinguished from and patentable over the prior art cited and of record.

The claimed method (as recited in independent Claims 39, 47, and 67 of the Application) requires, *inter alia*, the step of vacuum depositing a stent-forming metal onto a substrate under process conditions selected to minimize (or substantially eliminate) formation of chemical and intra- and inter-granular precipitates in the bulk material of the as deposited crystalline film.

Applicants submit that the concept of removing impurities from an elemental ingot is different from the concept of minimizing the formation of precipitates in a bulk material. As widely known to those skilled in the metallurgical arts, the term “precipitate<sup>1</sup>” is different from the term “microstructure<sup>2</sup>” and different from the term “impurity<sup>3</sup>.” In the metallurgical arts as

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<sup>1</sup> Online website <www.dictionary.com> defines the term precipitate as “a substance precipitated from a solution” and “to separate (a substance) in solid form from a solution, as by means of a reagent.”

<sup>2</sup> Online website <www.dictionary.com> defines the term microstructure as “the structure of a metal or alloy as observed, after etching and polishing, under a high degree of magnification.”

<sup>3</sup> Online website <www.dictionary.com> defines the term impurity as “the quality or state of being impure.”



they pertain to fabrication of biomaterials, and with particular reference to nickel-titanium shape memory alloys, precipitates are reaction products formed from a solid solution under increased thermal conditions which drive the precipitate from solution, resulting in formation of the reaction products outside the solid solution, *i.e.*, the metal crystalline structure.

Thus, a “precipitate” is not an “impurity.” Rather, it is a reaction product from the solid metal solution. Conversely, an “impurity” is not a “precipitate”. Indeed, on paragraph 37, *Whitcher* clearly notes that “other impurities, such as oxygen, that may be contained in the elemental ingot may be filtered away from the substrate with this method” [Emphasis added]. Based on Applicants’ meticulous reading, there is no description whatsoever in *Whitcher* indicating that the “impurities” described in *Whitcher* and referenced by the Examiner, actually refer to precipitates.

Additionally, *Whitcher* discloses removing an impurity from the elemental ingot which presumes that the impurity was initially present in the material. The impurity is removed from the ingot before the material is deposited onto the substrate. On the other hand, Applicants’ method requires preventing the formation of precipitates. Precipitates are prevented from forming in the bulk material before it is deposited onto the substrate. Thus, *Whitcher* and Applicants employ two different mechanisms; one of removal and one of preventing formation.

Furthermore, even assuming *arguendo* that *Whitcher*’s teaching of removing impurities from the elemental ingot is in some manner analogous to Applicants’ teaching of minimizing precipitate formation -- a position that Applicants strongly oppose--, the Final Office Action’s anticipation rejection would still be improper because *Whitcher* does not qualify as an enabling prior art reference with regard to Applicants’ pending claims. Courts have consistently held that for a prior art reference to anticipate a claimed invention, the prior art reference must be enabling. *See Amgen Inc. v. Hoechst Marion Roussel, Inc.* 314 F.3d 1313, 1354 (Fed. Cir. 2003) (stating that “a claimed invention cannot be anticipated by a prior art reference if the allegedly anticipatory disclosure cited as prior art are not enabled...a non-enabled disclosure cannot be anticipatory (because it is not truly prior art) if the disclosure fails to ‘enable one of skill in the art to reduce the disclosed invention to practice’” and quoting from *In re Borst*, 345 F.2d 851, 855 (C.C.P.A. 1962)).

Moreover, according to the Federal Circuit, “[t]o serve as an anticipating reference, the reference must enable that which it is asserted to anticipate” [Emphasis added]. *Elan Pharm, Inc. v. Mayo Dound. For Med. Educ. And Research*. 345 F.3d 1051, 1054 (Fed. Cir. 2003).

In the pending matter, *Whitcher* does not disclose precipitates or precipitate formation, let alone enable those skilled in the art to conduct vacuum deposition under process conditions selected to minimize formation of precipitates, as recited in independent Claims 39, 47, and 67. Simply put, Applicants submit that *Whitcher*’s mention of removing impurities from an elemental ingot or controlling the microstructure would not enable those skilled in the art to conduct vacuum deposition under process conditions selected to minimize precipitate formation.

Thus, for the reasons stated above, Applicants submits that pending Claims 39-53 and 67-74 are distinguished from the prior art cited and of record.

Applicants also assert that the publications provided as exhibits a and b are not prior art, as stated in the Final Office Action, as they were published after the filing date of the present application. Thus, contrary to the Final Office Action, Applicants do not need to file an information disclosure statement including the two exhibits.

### **Summary**

Accordingly, Applicants submit that the pending claims are patentably distinct from and over the art cited and of record. Favorable reconsideration of the rejection of the pending claims is solicited.

Any amendments made during the prosecution of this application are intended solely to expedite prosecution of the application and are not to be interpreted as acknowledgement of the validity of any rejection raised earlier in prosecution, nor as acknowledgement that any citation made against the application is material to the patentability of the application prior to amendment.

This Paper is being concurrently filed with a Request for Continued Examination and payment of the related filing fees. No additional fees are believed necessitated by the filing of this Paper. Should any such additional fees be required, the Commissioner is hereby authorized

to deduct them from Deposit Account No. 18-2000, of which the undersigned is an authorized signatory.

Should the Examiner believe that there are any outstanding matters capable of resolution by a telephone interview, the Examiner is encouraged to telephone the undersigned attorney of record.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'J. Paredes', written in a cursive style.

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December 3, 2012

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Docket No. 6006-015